REMARKS

Claims 1, 3, 5-10, 12 and 13 are pending in the present application. Claims 8 and 9 are withdrawn from consideration. Claims 1, 3, 5-10, 12 and 13 are rejected. Claims 12 and 13 are herein canceled. Claims 1 and 7 are herein amended. No new matter has been presented.

In amended claim 1, a hydrophilic polyol (B1) is limited to a polyether polyol (B1-l).

The added feature of a content of sodium, potassium and magnesium is supported by previous claim 7, and page 18, line 32 to page 19, line 5, and page 28, lines 10-15 in the specification.

Claim 7 is amended to remove a content of alkaline metals and alkaline earth metals.

Claim Rejections - 35 U.S.C. §112

Claims 1, 3, 5-10, 12 and 13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Within claim 1, the Examiner asserts that the phrase "including the polyether polyol (B1-1) *as an essential constitutional unit*" renders the claims indefinite because it is unclear if the language requires the polyether polyol to simply be present within polyol component (B) or if it requires that the polyether polyol be chemically incorporated into the polyester polyol. Furthermore, it is unclear how to interpret the use of the word, "essential", and it is unclear how the word further limits the claims.

Applicant herein amends claim 1 to remove the language "...including the polyether polyol (B1-1) as an essential constitutional unit". Therefore, Applicant submits that the rejection is overcome and should be withdrawn.

Claim Rejections - 35 U.S.C. §103(a)

Claims 1, 3, 5-7, 10, 12 and 13 remain rejected under 35 U.S.C. §103(a) as being unpatentable over WO 03/051952 in view of Hiraishi et al. ('266) or Nakamura et al. (U.S. 2003/0225239)or Sparer et al. (U.S. 2004/0033251) or Felt et al. (U.S. 2005/0060022).

The Examiner notes Applicant's argument that showings of unexpected results rebut the *prima facie case* of obviousness and have further argued that their amendments render the argued showings commensurate in scope with the claims.

In response, the Examiner asserts that the showings remain insufficient to rebut the *prima facie* case of obviousness.

Applicant reemphasizes that data has been presented data in the original specification, and then in the Declarations filed on December 26, 2007, February 26, 2009, June 26, 2009 and August 20, 2009. The results presented extend the range of constituents that are shown to be supported as part of the present invention.

Applicant herein amends the claims to clarify the invention. Thereafter, Applicant respectfully disagrees with the rejections and submits that the rejection has been overcome upon a demonstration of unexpected results associated with the claimed invention.

In amended claim 1, a hydrophilic polyol (B1) is limited to a polyether polyol (B1-1).

Claim 7 is amended to remove a content of alkaline metals and alkaline earth metals.

The Examiner asserts that the examples continue not to be commensurate in scope with the claims. The Examiner still asserts that Applicant's examples are limited to *specific* polyol compounds having *specific* characteristics, such as specific metal contents, but the claims are not so limited. However, Applicant respectfully disagrees for the following reasons.

(1) Fluorine-containing aliphatic diisocyanate (A11)

Applicant has disclosed (A11) having 5 to 12 carbon atoms (Rf having 3 to 10 carbon atoms) in Example and Declarations. Thus, Applicant submits that the noted examples and data are commensurate in scope with the claims.

(2) Polyol component (B) having a hydrophilic polyol (B1)

By present amendment, Applicant has removed (B1-2) from claim 1.

Concerning a hydrophilic polyol (B1), Applicant has disclosed a random co-adduct of ethylene oxide/propylene oxide in Examples 1, 2 and 17-27 and mixture of the random co-adduct of ethylene oxide/propylene oxide and the adduct of propylene oxide in Examples 3-9, 16 and 17.

Thus, Applicant submits that the noted examples and data are commensurate in scope with the claims.

(3) Specific metal contents

Applicant has defined the specific metal contents of sodium, potassium and magnesium. Applicant notes that because potassium hydroxide, sodium hydroxide and synthetic magnesium silicate are used in the Examples, the noted examples and data are commensurate in scope with the claims.

(4) Phenolic radical scavenger (PRS)

Applicant has listed the phenolic radical scavengers used in Example and Declarations. Thus, the noted examples and data are commensurate in scope with the claims.

Phenolic radical scavengers (PRS) yields unexpected results

Applicant notes that it is required for the medical adhesive to show excellent wet adhesive strength at 2 hours later ("2H" in Example) immediately after applying the medical adhesive. Furthermore, it is also required for the medical adhesive to maintain the excellent wet adhesive strength for about one week ("5D" in Example) because it takes about one week to make tissues start repairing.

When a medical adhesive comprises an urethane prepolymer obtained by reacting usual isocyanate (e.g. TDI, HDI, HMDI etc), the medical adhesive has a wet adhesive strength of less than 1 kg/cm at 2H and 5D, irrespective of presence of PRS (as noted in comparative examples 6-11 in the declaration filed on December 26, 2007). These comparative examples 6-11 mean that presence of PRS does not affect continuity of the wet adhesive strength.

On the other hand, when a medical adhesive comprises a urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates, the medical adhesive cannot maintain the sheetshape at 5D without the presence of PRS (as noted in comparative example 1).

In the present invention, both of the urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates and PRS are used (Examples 1-27) and the medical adhesive has high wet adhesive strength of more than 1 kg/cm at 5D. The adhesive strength in at 5D is higher than the adhesive strength measured in comparative examples 6-11.

That is, only when both of the urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates and PRS are used, the medical adhesive has excellent wet adhesive strength that is superior to a medical adhesive comprising an urethane prepolymer obtained by reacting usual isocyanate.

Furthermore, Applicant has shown that antioxidants other than PRS are not effective to obtain the medical adhesive having excellent wet adhesive strength (comparative examples 3 and 4).

Applicant agrees with the Examiner that PRS within polyurethanes was known at the time of invention.

However, Applicant argues that the object of PRS added in the medical adhesive in the present invention is completely distinguishable from the object of PRS added in the known polyurethanes.

Applicant attaches a reference paper and three reference patent documents to show the object of PRS added in the known polyurethanes.

Paper 1: Patrick Vermette, Hans J. Griesser, Gaetan Laroche and Robert Guidoin; TISSUE ENGINEERING INTELLIGENCE UNIT 6-Biomedical Applications of Polyurethanes, LANDES BIOSCIENCE, EUREKAH.COM, January 2000.

Patent documents 1: US Patent 5,359,129, published on October 25, 1994.

Patent documents 2: US Patent 5,258,548, published on November 2, 1993.

Patent documents 3: US Patent 3,428,598, published on February 18, 1969.

The conventional object of PRS added in the known polyurethanes is to prevent changing in physical properties of the polymer surface, e.g., loss of glass, yellowing and cracking (see the boxed text in page 57 of Paper 1). Pages 57-67 of Paper 1 show PRS is effective to prevent polyurethanes from causing yellowing.

Similar yellowing (coloration) of the polyurethanes is described in Patent documents 1, 2 and 3. Applicant notes the boxed text in each of patent documents.

Namely, it is known not only that the polyurethanes without the presence of PRS tend to cause yellowing but also that the yellowing can be prevented by adding PRS to the polyurethanes.

Applicant emphasizes that the yellowing is a minor change of the condition of the polymer surface. Therefore, the object of PRS added in the known polyurethanes is to prevent the minor change of the condition of the polyurethane polymer.

On the other hand, the present inventors have found that a medical adhesive comprises a urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates without the presence of PRS cannot maintain the sheet shape at 5D (part or all of the sheet have changed into viscous liquid). The results are clearly shown in comparative examples 1 to 4. These results are

not a minor change, but rather a major and heretofore unexpected change of the condition of the polyurethane polymer. Moreover, the present Inventors have found that the major change of condition causes only in the urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates.

Furthermore, the Inventors have found that PRS is effective to prevent the major and unexpected change of condition which causes only in the urethane prepolymers obtained from fluorine-containing nonaromatic polyisocyanates. Therefore, the object of PRS added in the medical adhesive in the present invention is not to prevent yellowing and completely distinguishable from the object of PRS added in the known polyurethanes.

Although there are a great number of antioxidants, including PRS, only PRS is effective to prevent the major change noted above. Applicant has already shown that antioxidants other than PRS are not effective to solve the problem (as note, for example, in comparative Examples 3 and 4). Therefore, the effect obtained by using PRS would have been unpredictable from any prior arts.

Taking into account these considerations, Applicant concludes that the effect exerted by combining the urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates and PRS represent unpredictable results for one of ordinary skill in the art at the time of the invention. Therefore, the present invention is not obvious in view of the cited references.

In view of the aforementioned amendments and accompanying remarks, Applicant submits that the claims, as herein amended, are in condition for allowance. Applicant requests such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact the undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely, Applicant petitions for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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Enclosures Reference Paper 1: Patrick Vermette, Hans J. Griesser, Gaetan Laroche and Robert Guidoin; TISSUE ENGINEERING INTELLIGENCE UNIT 6 - Biomedical Applications of Polyurethanes, LANDES BIOSCIENCE, EUREKAH.COM, January 2000
Reference Patent 1: US Patent 5,359,129, published on October 25, 1994.
Reference Patent 2: US Patent 5,258,548, published on November 2, 1993.
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